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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,008	04/12/2005	Boris Y Shekunov	FER-14650.001.001	2702
7609 7590 01/23/2008 RANKIN, HILL & CLARK LLP 925 EUCLID AVENUE, SUITE 700 CLEVELAND, OH 44115-1405			EXAMINER DRODGE, JOSEPH W	
			ART UNIT 1797	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/531,008

Applicant(s)

SHEKUNOV ET AL.

Examiner

Joseph W. Drodge

Art Unit

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 4-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 4-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>05042006</u> . | 6) <input type="checkbox"/> Other: _____ |

Claims 1 AND 4-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Explicit or sufficient support for claiming of the supercritical fluid being in the absence of any solvents and the collection vessel being maintained above the boiling point of the solvent and volatilizing the solvent could not be found in the instant Specification; thus these added recitations to the independent claims constitute New Matter.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1,4-11 and 13-21 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,986,846 in view of Sievers et al patent 5,639,441. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims. The instant claims and claims of '846 commonly disclose a method of producing particles employing supercritical fluid mixed with load material to form a melt, and eventual expansion of the melt into a vessel or chamber to convert fluid to volatize or form a gas, thus forming particles. The instant claims primarily differ in omitting use of mixing chambers in series and in adding the limitation of formation of two factions from a mixed solvent. However, Sievers discloses both such facets in formation of particles employing supercritical fluid (see claim 1 of Sievers) so as to facilitate industrial production of the particles.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 12 and 22 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Patel et al patent 6,248,363 or Sievers et al patent 6,630,121. Claims 12 and 22 define the product by how the product was made. Thus, claims 12 and 22 are product-by-process claims. For purposes of examination, product-by-process claims are not limited to the manipulation of the recited steps, only the structure implied by the steps. See MPEP 2113. Patel et al (column 45, line 42-column 46, line 11) and Sievers et al (column 14, lines 18-24) both disclose composite particles manufactured from melts and employing use of supercritical fluid, solvent and precipitation by expansion into particles. The references suggests such a product.

When the reference teaches a product that appears to be the same as, or an obvious variant of, the product set forth in a product-by-process claim although produced by a different process. See *In re Marosi*, 710 F.2d 799, 218 USPQ 289 (Fed. Cir. 1983) and *In re Thorpe*, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). See also MPEP § 2113.

When the examiner has found a substantially similar product as in the applied prior art, the burden of proof is shifted to applicant to establish that their product is patentably distinct and not the examiner to show the same process as making. *In re Brown*, 173 USPQ 685 and *In re Fessmann*, 180 USPQ 324. **Also now see In SmithKline Beecham Corp. v Apotex Corp. Federal Circuit 02/24/2006, where it**

was held that process limitations in product by process claims are not positively recited limitations.

Claims 1,4-11 and 13-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patel et al patent 6,248,363 in view of Sievers et al patent 5,639,441 and Sievers et al patent 6,630,121. Patel et al disclose producing composite particles from pharmaceutical feed mixtures comprising particles that are formed into melts, method steps employing supercritical fluid, solvents, solutes, formation of masses, and expansion/evaporation/volatization/ steps to form the composite particles. See especially column 37, line 27-column 38, line 22 and column 39, line 12-column 40, line 52 regarding employ of polymeric, waxy, solute and solvent ingredients; column 41, line 55-column 42, line 13 and column 45, line 42-column 46, line 11 concerning formation of melts and final processing into composite particles.

The claims all differ in requiring mixing of the other melt ingredients with first supercritical fluid followed by addition of a solvent that is at least partially miscible/soluble with the supercritical fluid. The claims also require that the contacting with fluid and solvent and the expansion/volatization etc. be in separate vessels in series, and that the solvent and supercritical fluid be vaporized out, etc. However, Sievers '441 produces pharmaceutical particles by steps of sequentially mixing the ingredients with supercritical fluid and then with a miscible solvent, followed by expansion/pressure drop, etc. in separate chambers or vessels (see especially column 10, lines 27-52). Sievers '121 employ the Sievers '441 process steps (incorporates by reference, see column 1, line 65-column 2, line 14) and applies them to form particles comprised of melts, supercritical fluid and solvent (column 14, lines 18-33). It would have been obvious to have

employed the process steps of Sievers et al '441/Sievers et al '121 in the Patel et al process, to facilitate production of particles of better-controlled and more uniform particle size ranges and to facilitate industrial scale-up of the particle production process.

Regarding dependent claims ingredients of the produced particle feed material and choice of supercritical fluids, solvents, and solute or carrier material, active materials/active ingredients, solvent/solute ratios, additional use of surfactants and the recited size ranges of the produced particles are further taught in Patel et al at columns 37-40 and Sievers '441 at column 5, lines 12-58 and column 6, lines 5-61.

Shine et al patent 5,766,637; Park et al patent 6,767,637 and Yeo patent 6,599,624 are of general interest for discussions of production of pharmaceutical particles from material mixtures employing melts and using solvents and supercritical fluid.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Drodge at telephone number 571-272-1140. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Roy Sample, can be reached at 571-272-1376. The fax phone number for the examining group where this application is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either private PAIR or Public PAIR, and through Private PAIR only for unpublished applications. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JWD
January 18, 2008

/Joseph Drodge/
Primary Examiner, Art Unit 1797